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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,014	12/12/2003	Audrey Goddard	10466/486	2599

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,014	GODDARD ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/26/2007 has been entered.

Status of Application, Amendments, And/Or Claims

Claims 22-26 are pending and under examination.

Response to Arguments

Claim Rejections - 35 USC § 101 & 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 22-26 under 35 U.S.C. § 101 is maintained for the reasons of record as set forth in the office action mailed on 9/19/2007.

The rejection of claims 22-26 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth on pages 2-4 in the office action mailed on 9/19/2007.

The instant claims are drawn to an isolated antibody that binds to the polypeptide of SEQ ID NO: 83 and that the antibody is a monoclonal or humanized antibody, which is labeled.

Applicants reiterate their arguments (page 3 of Response) that the MLR assay is art recognized for identifying molecules which suppresses an immune response. They argue that the results obtained from MLR assays are generally predictive of their in vivo effectiveness (page 4). Applicants argue (page 6 of Response) that Example 34 of the instant specification discloses that the PRO361 polypeptide tested positive in the Mixed Lymphocyte Reaction (MLR) Assay. Applicants argue (page 5 of Response) that the MLR assay described in the present specification is a comparative assay, meaning that the utility of PRO361 demonstrated by this assay is based upon a comparision of relative expression levels between a known molecule and the unknown PRO361 molecule. Applicants argue that the difference in response between known molecule and unknown molecule in the MLR assay could provide useful information. They argue that MLR assay could identify molecules that could be used to suppress the graft versus host response. Applicants argue (page 3 of Response) that no case, rule or statute requires explicit data values to support an applicants's assertion of utility. Applicants argue that a sufficient correlation between the tests and an asserted pharmacological activity is needed to convince those skilled in the art to a reasonable probability that the

novel compound will exhibit said asserted pharmacological behavior. Applicants argue (page 6 of Response) that the standard for assessing immunosuppressive ability in the instant application is same as in US Patent No. 7,220,835 or in US Patent No. 7,282,570. On page 6 of Response, Applicants argue that the instant specification establishes a utility of PRO361 by disclosing that the polypeptide PRO361 is positive in the MLR assay. Therefore, the polypeptide is useful as an immunosuppressive agent. Applicants argue that the Fong declaration details the state of the art in the field of immunostimulation/suppression.

Applicants' arguments have been fully considered but they are not persuasive because the mixed lymphocyte culture (MLC or also known as MLR) is a special case of antigen stimulation in which T lymphocytes respond to foreign histocompatibility antigen on unrelated lymphocytes or monocytes. The previous office action of 2/7/2007 clearly acknowledges the MLR assay being useful for screening compounds that could have role in immune response (see pg.3). However, Applicants' assertions that the claimed invention could be useful for the treatment of immunological conditions because the specification at page 141, lines 33-35, states "any decreases below control is considered to be a positive result for an inhibitory compound, with decreases of less than or equal to 80% being preferred" are not persuasive. The ability of the claimed protein to stimulate or inhibit lymphocyte proliferation in the MLR assay does not provide support for what specific conditions or for which specific diseases the claimed invention would predictably function for a therapeutic suppression of the immune system. Therefore, the results of the MLC or MLR assay in the instant specification are

merely preliminary and do not support a specific and substantial utility for the claimed invention. Further, one of ordinary skill in the art would not conclude that a molecule which tested positive in the assay (page 141 of the specification) wherein "any decreases below control is considered to be a positive result for an inhibitory compound" would be useful as a molecule in preventing suppression of immune response in an individual (asserted use). Applicants arguments that the reference Fung-Leung et al (Transplantation: 60, 362-8, 1995) teaches a MLR assay could be used for predicting a compound's utility in tissue graft rejection has been fully considered but they are not persuasive because Fung-Leung discusses a dose response curve of Tepoxalin in MLR assay and teaches that Tepoxalin with IC50 of 1.3 uM when tested in 50 mg/kg/day prolongs skin graft from 10.5 days to 15 days (abstract). Fung-Leung et al teach that Tepoxalin at doses 12.5 mg/kg/day and 25/mg/kg did not have a significant effect in prolonging graft rejection (page 365, left column). However, the instant specification is devoid of any such data on MLR assay and graft rejection. There is insufficient data presented to conclude anything regarding the ability of an antibody that binds to the polypeptide PRO361 of the invention to be used in a substantial way to therapeutically inhibit an immune response, and much more experimentation would be required to use the invention in this manner. In regard to Applicants argument that the instant invention and US Patent No. 7,220,835 or allowed US Patent application No. 10/213,181 use same standard for assessing immunosuppressive ability of a test protein is not persuasive because each application is examined on its own merit and support therein.

Further, in response to Applicants' arguments regarding the Fong's declaration, the Examiner has fully considered but they are not persuasive for the reasons of record in pages 4-6 of 11/1/2005 office action.

Conclusion

No claim is allowed.

No new rejections have been made, and no new evidence has been cited. THUS, THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
Art Unit 1646
15 December 2007
Fax: 571-273-2922

/Robert Landsman/
Primary Examiner, Art Unit 1647